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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/520,100 | 01/04/2005 | Masaya Tanaka | 0020-5551PUS1 | 6992 |
| 2292 7590 11/19/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | | |
| EXAMINER | | | | |
| KASSA, TIOABU | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1619 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 11/19/2009 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/520,100

Applicant(s)

TANAKA, MASAYA

Examiner

TIGABU KASSA

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the amendment filed July 16, 2009. Claims 25-36 are pending. Claims 25-36 are under consideration in the instant office action. Claims 1-24 are cancelled. Applicant's amendment has necessitated a new ground of rejection. Accordingly, this Action is made FINAL.

Note: The examiner notes that independent claims 25 and 31 are broader in scope than the now cancelled claims since they no longer indicate that carbon dioxide is substantially in a non-bubble state.

Moot Rejections/Objections

The rejection of claims 13-24 cited in the previous office action mailed on January 16, 2009 are moot, because said claim(s) has/have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "sheet-like" in claim 26 and 32 is vague and indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining what type of materials "sheet-like" refers to. One of ordinary skill in the art would not be reasonably apprised of the scope of the meaning of the term.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically taught or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (WO 99/24043) using (U.S. patent No. 6,689,339 as translation of WO 99/24043) in view of Gibbins et al. (WO 01/49258, which incorporates by reference Gibbins et al. US Patent 5928174 and Nangia et al. US Patent 5196190).

Applicant Claims

Applicants claim a combination of materials for preparing an external preparation containing carbon dioxide comprising: a base agent that comprises a nonwoven cloth made of an elastic polymeric three- dimensional network structure impregnated with a viscous material containing an acid and water, wherein the base agent is adapted to contact with skin during use; and a reactant that contains a carbonate, and is adapted to contact with the base agent during use so as to generate carbon dioxide, wherein the formulation of the reactant is selected from a viscous liquid, an ointment, a cream, a paste and a fluid hydrogel.

Applicants also claim an external preparation containing carbon dioxide comprising: a base agent that comprises a nonwoven cloth made of an elastic polymeric three- dimensional network structure impregnated with a viscous material containing an acid and water, wherein the base agent is adapted to contact with skin during use; and a reactant that contains a carbonate in contact with the base agent so as to generate carbon dioxide, wherein the formulation of the reactant is selected from a viscous liquid, an ointment, a cream, a paste and a fluid hydrogel.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Tanaka et al. teach “viscous compositions containing carbon dioxide, formed by incorporating carbon dioxide in the form of bubbles in a water-containing viscous composition containing one or more thickener(s)” (column 2, lines 37-41) for mucocutaneous or transmucosal absorption of carbon dioxide. Tanaka et al. also teach kits for carbon dioxide external use, comprising carbonate salt and a water-containing viscous composition (column 3, lines 40-45). Tanaka et al. also state that the “carbon dioxide is generated by a reaction between an acid and a carbonate salt (column 3, lines 14-18). Tanaka et al. also teach that the composition may be

applied to a part of the body directly, by impregnating the viscous composition using an absorbent material such as a gauze or sponge (column 11, lines 4-5). Tanaka et al. teach a kit comprising an acid-containing aqueous viscous composition and carbonate-containing sheet (column 6, lines 60-61).

Tanaka et al teach a material for formation of a carbon dioxide external preparation that includes a viscous material containing at least an acid and water (column 3, lines 39-40) and a reactant that contains carbonate (column 3, lines 39). Prior to use, the carbonate is reacted with the viscous material which produces a carbon dioxide containing product and the product is contacted with skin using a gauze or sponge that is impregnated with the product (column 11, lines 4-6), which renders obvious instant claim 25, 27, 31 and 33.

As per the disclosure by Tanaka et al. for the possibility of impregnating the viscous composition using an absorbent material such as a gauze or sponge or by patching a bag made of the absorbent material wherein the composition is filled (column 11, lines 4-6), a sponge is a polymeric three-dimensional network, which can be sheet-like, fibrous or porous absorbent, which renders obvious instant claims 26 and 32.

The amount of acid in the aqueous viscous composition may be 0.01-30 parts by weight (column 12, lines 50-52). In examples 97-105, the amount of acid is 2% and the amount of carbonate (either sodium bicarbonate or sodium carbonate) is 2.4 % which corresponds to 1.2 parts by weight to 1 part by weight of acid which renders obvious instant claims 28 and 34.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Tanaka et al does not explicitly teach the viscous material being initially impregnated in an elastic polymeric three-dimensional network structure prior to reacting it with the carbonate. This deficiency is cured by the teachings of Gibbins et al.

Gibbins et al teach matrices such as polyacrylamide and a non-gellable mucopolysaccharide, which are polymeric three-dimensional network structures, being used to trap a gas generated after a reaction between two different reactants (page 18, lines 7-11). Gibbins et al (WO 01/49258) teach that the gas bubbles are generated by the permeation of the second reactant added to the formed matrix that contains the first reactant (page 18, lines 13-14). The reaction between the two reactants *in situ* results in the liberation of gas which is **entrapped within the matrix** (page 18, lines 14-16). Acryderm®, used by Gibbins et al. to form the matrix is water absorbent, **elastic**, and oxygen permeable polymeric material (page 29, lines 22-23 and line 26). The matrix of Gibbins et al. is, therefore, an elastic polymeric three dimensional network structure. Gibbins et al (WO 01/49258) also teach the possibility of incorporating an active agent with the second reactant, which is similar to the viscous composition in the instant application (page 18, lines 10-11). Gibbins et al (WO 01/49258) also mention that the composition can be added to the **preformed matrix either simultaneously or sequentially, for perfusion within the matrix** (page 21, lines 20-23). The formed matrix is then **placed in the presence of the second reactant for the reaction to proceed so as to form the gas bubbles** (page 18, lines 14-16). Gibbins et al (WO 01/49258) also specifically teach the possibility of generating of **carbon dioxide gas within the matrix by reacting an acid catalyst which is incorporated in the matrix followed by the perfusion of the matrix with a carbonate** (page 15, lines 10-12).

Gibbins et al., in US Patent 5928174, teach the thickness of the flat sheet matrix material is 0.9 mm (example 1, column 9, line 22) which addresses the limitations in claims 30 and 36.

Nangia et al., in US Patent 5196190, teach the diameter of the casting apparatus to be 70 mm in diameter which corresponds to a 38 cm² surface area. Using the same casting apparatus/sheet mold to make the specifically preferred composition taught by Gibbins et al. on page 14, lines 17-25, which has a dehydrated mass of 0.6g corresponds to 0.016 g/cm² which lies in the instantly claimed range found in claims 29 and 35.

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to made to impregnate the viscous composition of Tanaka into an elastic three-dimensional polymeric network structure prior to reacting it with carbonate salt in stead of impregnation of the viscous composition for the liberation of carbon dioxide for external use into the sponge after reacting the viscous composition containing an acid with the carbonate salt, because Gibbins et al. as discussed above teach the recited mechanism. An ordinary skilled artisan would have been motivated to impregnate the viscous composition of Tanaka into a sponge prior to reacting it with carbonate salt, because the mechanism will help to eliminate the mixing prior to the impregnating as suggested by Gibbins et al. One of ordinary skill in the art at the time of the instant application was filed would have had a reasonable expectation of success upon combining Tanaka et al and Gibbins et al, because both prior arts teach similar materials for the delivery of gaseous agents such as carbon dioxide via *in situ* production.

The optimization of the dimensions of the three-dimensional network structure and amounts of viscous material per square centimeter of the three dimensional network structures

are within the purview of the skilled artisan since dressings for the application of gases to a treatment site are known in the art. Details of forming sheets of the elastic polymeric structure using sheet molds are found, for example, on page 14, lines 17-25 of Gibbins et al. Using the information found in US Patents 5196190 and 5928174 which are incorporated by reference would result in the composition/preparation which has the instantly claimed thickness and grams of viscous material per square centimeter. Therefore, the optimization of the dimensions of the three-dimensional network structure and amounts of viscous material per square centimeter is both obvious and reasonably likely to succeed. The skilled artisan would be motivated to include sufficient amounts of viscous material and to optimize the thickness in order to ensure sufficient amounts of the carbon dioxide reached the application site.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 07/16/09 have been fully considered but they are not persuasive. Applicants argue that Tanaka et al. teach compositions which contain carbon dioxide bubbles and that Tanaka et al. fails to teach a means for suppressing bubble formation. However, the instant claims do not specify carbon dioxide bubbles or the lack thereof.

The declaration provided by applicants compares the extent of bubble formation and the extent of vasodilation with the preparation of Tanaka et al. However, the instantly claimed invention does not contain limitations regarding either the extent of bubble formation or the extent of vasodilation. Moreover, the comparative experiments were conducted using the preparation of Tanaka et al. and not over the obvious variation of Tanaka et al. in view of Gibbins et al.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants also argue that the generation of carbon dioxide occurs outside the gauze or sponge in Tanaka et al. versus inside the nonwoven cloth. This limitation is addressed by Gibbins et al. (WO01/149258).

Applicants also argue that Tanaka et al. do not teach an "elastic" polymeric structure. This is not persuasive because examples given in the applicants' specification use either a sponge or a nonwoven cloth. Although applicants use the word "elastic" in claims 25 and 31, the instant specification (e.g. page 9, lines 12-13) clearly indicates sponges are suitable polymeric three-dimensional network structures. Therefore, the examiner concludes that the sponges taught by Tanaka et al. (column 11, lines 5-6) constitute elastic polymeric three-dimensional network structures as the term is used in the instant application. Moreover, the matrix of Gibbins et al. is elastic and constitutes an elastic three-dimensional polymeric network structure (page 29, lines

22-23 and line 26). Therefore, both Tanaka et al. and Gibbons et al. teach elastic polymeric three-dimensional network structures.

Applicants argue that Gibbins fails to address the acidic pH of the composition to suppress bubble formation. However, the pH is not a limitation found in the instantly claimed invention. The examiner notes that although instant claims 28 and 34 specify the ratio of carbonate to acid, this does not specify the pH of the composition since the pH would also depend, for example, on the particular acid used in the composition. Moreover, Gibbins teaches the incorporation of an acid catalyst in the matrix for the formation of carbon dioxide with carbonate (page 15, line 10). The examiner also notes that the affect of both pressure and pH on the solubility of carbon dioxide are well known in the art.

Applicants argue that Gibbins fails to make up for the deficiencies of Tanaka et al., however, Gibbins does teach the incorporation of acid into the matrix followed by addition of carbonate to generate carbon dioxide within the matrix. Applicants also argue that Gibbins is further removed from the instantly claimed invention than Tanaka. However, Gibbins is clearly related to the instantly claimed invention since Gibbins teaches matrices for the delivery of gases including carbon dioxide to tissues.

Applicants argue that none of the references (Tanaka or Gibbins) recognize the surprising or unexpected properties of the instant invention. The examiner read the declaration submitted on 7/16/09 and finds comparative results relating to the extent of bubble formation and vasodilation. However, limitations regarding the extent of bubble formation and vasodilation are not found in the instant claims. Moreover, applicants must address the difference between the instantly claimed invention and the obvious variation of Tanaka et al. in view of Gibbins. The

examiner does not know of any other unexpected properties or results in the instant specification. The examiner also notes that although the vasodilation properties of carbon dioxide not a limitation in the instantly claimed invention, the vasodilation properties has been known for decades as evidenced by Ito et al. "Topical Application of CO₂ Increases Skin Blood Flow." J Invest Dermatol 1989, 93, 259-262.

Conclusion

Claims 25-36 are rejected. Claims 1-24 are cancelled. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa
/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619

11/05/09